

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent application of:

Applicant(s): Horace W. Hale et al.  
Serial No: 10/651,871  
Filing Date: August 29, 2003  
Title: FACET IMPLANT  
Examiner: David Comstock  
Art Unit: 3733  
Docket No. HORA.P0101US

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

MS AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal, and the review is requested for the reasons stated on the attached sheets.

In the event any fee or additional fee is due in connection with the filing of this paper, the Commissioner is authorized to charge those fees to our Deposit Account No. 18-0988 (under the above Docket Number).

Respectfully submitted,

RENNER, OTTO, BOISSELLE & SKLAR, LLP

By /Mark C. Johnson/

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ADDENDUM TO PRE-APPEAL BRIEF REQUEST FOR REVIEW

***Rejections - 35 U.S.C. § 102(e)***

Claims 1-2, 4-11, 14-20, 41-61 and 63 were rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Reiley (US Patent Publication Number 2002/0123806; cited by Applicant). It is respectfully requested that Reiley does not teach or suggest the limitations of any of the pending claims.

According to the Examiner, the “claims do not require that the facet be a natural facet.” (Advisory Action, p. 2). The Examiner could not be more wrong. Of course the claims are limited to a device for use with a natural facet. The claims refer to a “superior articular facet” and an “inferior articular facet” both of which are terms of art readily understood by those of ordinary skill in the art to mean structures of vertebrae. Moreover, the specification of the application specifically defines these terms with reference to the human spine. (Page 5, lines 18-22; Fig. 3).

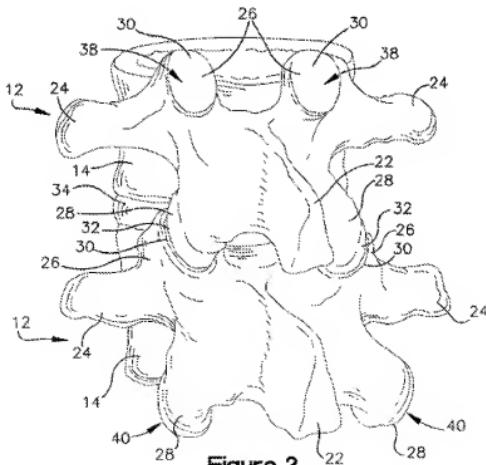
Moreover, the Examiner never addressed the Applicant’s argument that the joint elements of Reiley are not “configured for placement on” an articular facet. Rather, the Examiner appears to contend that somehow this limitation is met by Reiley merely because “Reiley calls elements 34 and 76 facet joint elements” and “[e]ach of the elements comprises articulating facet joint implant structure.” (Advisory Action, p. 2). Obviously, the claim cannot be construed so broadly as to cover all structures referred to as “facet joint implants” that form an “articulating facet joint structure.”

Instead, the present invention relates to providing an artificial articulating surface on a facet (inferior and/or superior). Independent claims 1, 14, 20 and 53 each all recite implants “**configured for placement on**” an **articular facet**. And independent claims 41, 47 and 63 all recite “**providing an artificial articulating surface on**” an **articular facet**. Reiley does not disclose any implant configured for placement on an articular facet, nor does Reiley disclose any method for providing an artificial articulating surface on an articular facet. Instead, Reiley discloses a facet replacement system. None of the structures disclosed in Reiley are capable of being placed on an articular facet. In fact, Reiley teaches away from the claimed invention because Reiley requires the resection of the articular facet being treated.

### Anatomy of the Lumbar Spine

As explained in the background section and illustrated in Figure 3 of the present application, the laminae of the spine have various structures, including the superior facet, inferior facet, superior articulating surface and inferior articulating surface. Notably, structures 30 and 32 of Figure 3 are the "articular facets" referenced in the claims of the present invention:

The transition from the pedicles 16 to the laminae 20 is interrupted by a series of processes. Two transverse processes 24 thrust out laterally on each side from the junction of the pedicle 16 and the lamina 20. The transverse processes 24 serve as guides for the attachment of muscles to the vertebrae 12. Four articular processes, two superior 26 and two inferior 28, also rise from the junctions of the pedicles 16 and the laminae 20. The superior articular processes 26 are oval plates of bone rising upward on each side from the union of the pedicle 16 with the lamina 20. The inferior processes 28 are oval plates of bone jutting downward on each side. The superior and inferior articular processes 26 and 28, respectively, each have a natural bony structure known as a facet. The superior articular facet 30 faces upward, while the inferior articular facet 32 faces downward. The superior articular facet 30 and the inferior articular facet 32 have articulating surfaces 38 and 40, respectively.



**Figure 3**

Bogduk, Nikolai, Clinical Anatomy of the Lumbar Spine and Sacrum, 4<sup>th</sup> ed. Elsevier, Churchill, Livingstone; 2005 is also instructive:

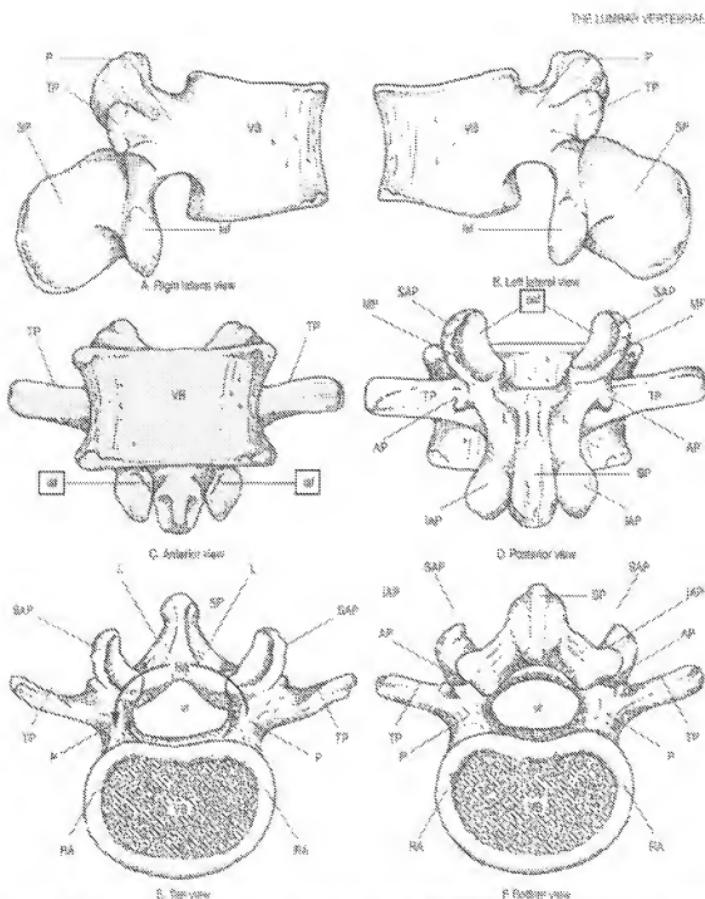


Figure 1.2 The parts of a typical lumbar vertebra: AP, accessory process; IAP, inferior articular process; IAP, inferior articular process; L, lamina; MP, mammillary process; RA, neural arch; P, process; TP, transverse process; SAP, superior articular process; SP, spinous process; TP, transverse process; VB, vertebral body; Vf, vertebral foramen.

## Reiley

Unlike the present invention, Reiley is directed to an apparatus that *replaces* the articular facet, not an apparatus configured for *placement on* an articular facet.

Figures 1 and 2 of Reiley are depictions of vertebrae and Figures 3-5 and 7-9 illustrate the devices of Reiley as they are used to treat vertebrae. It is clear in each of Figures 3-5 and 7-9 that the entire facet (superior or inferior) is resected and replaced with the apparatus of Reiley.

To remove any doubt regarding the nature of the Reiley device, Reiley explains throughout the specification that the prosthetic system replaces facet structures. Reiley refers to replacing the caudal portion or cephalad portion of the facet joint. As Reiley explains, this means either the entire superior half of the joint or the entire inferior half of the joint. (¶13).<sup>1</sup> Indeed, from Reiley's definition of the "caudal portion" and "cephalad portion" of the facet joint, it is clear that Reiley discloses only a system for replacing either the entire superior half of the joint or the entire inferior half of the joint. (¶¶1, 15, 16, 17, 18, 19, 39, 60, 64, 70, 73).

Reiley also makes clear that the disclosed apparatus is configured for attachment to the lamina and pedicle, and thus not placed on the inferior or superior facet. (¶98).

Finally, Reiley leaves no doubt that the superior or inferior facet **must be removed** in order to install the apparatus:

"...because the caudal portion of the natural facet joint has been removed, the artificial facet joint structure of the caudal prosthesis 26 can be installed in a desired position...." (¶66, emphasis added).

"Because the cephalad portion of the natural facet joint is removed..." (¶74, emphasis added).

"As fig 9 shows, the caudal prosthesis 26, e.g. as described above, may also be installed with the cephalad prosthesis 48, to replace both the caudal and cephalad portions of the natural facet joint, after both caudal and cephalad portions of the natural facet joint are surgically removed. Together, the caudal and cephalad prostheses 26 and 48 form a total facet replacement system 52." (¶75, emphasis added).

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<sup>1</sup> Applicant's response to the August 18, 2009 Office Action includes block quotes of the cited portions of the specification of Reiley.

"Because the system 52 entails **removal of both** the caudal and cephalad **portions of the natural facet joints,...**" (¶76, emphasis added).

Clearly, the device disclosed in Reiley is not capable of being placed on an articular facet, nor is it capable of providing an artificial articulating surface on an articular facet. Any device that requires removal of the superior articular facet and/or the inferior articular facet certainly cannot be "**configured for placement on**" or capable of "**providing an artificial articulating surface on**" an **articular facet** as set forth in claims 1, 14, 20, 41, 47, 53, or 61.<sup>2</sup> Accordingly, it is submitted that claims 1-2, 4-11, 14-20, 41-61 and 63 are in condition for allowance.

#### ***Rejections - 35 U.S.C. § 103***

Claims 3, 12 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Reiley. For the reasons discussed above, Reiley does not meet the limitations of the independent claims. Accordingly, it is respectfully submitted that claims 3, 12 and 13 are in condition for allowance.

#### ***Conclusion***

It is submitted that this application is in condition for allowance and an early action to that effect is earnestly solicited. In the event that the Examiner has any questions regarding the arguments presented herein, the Examiner is invited to contact the Applicant's representative.

Respectfully submitted,

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<sup>2</sup> Indeed, a third party declarant provided an explanation of differences between the claimed invention and devices such as Reiley. (Declaration of John S. Sherman filed with the June 7, 2006 Amendment, p. 2). Notably, the Examiner did not consider Reiley to be relevant at that time, even though it had been previously submitted and reviewed.